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In re application of :

Teruaki SEKINE et al. : Docket No. 01208/P-502(PCT/US)

Serial No. 09/214,848 : Group Art Unit 1616

Filed January 14, 1999 : Examiner F. Choi

COMPOSITIONS FOR VIRAL INFECTIONS, :
PROCESS FOR PREPARING THE SAME,
AND METHOD FOR PREVENTING/TREATING
VIRAL INFECTIONS (AS AMENDED)

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEES FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975

2-22-01

REQUEST FOR RECONSIDERATION

Assistant Commissioner for Patents,
Washington, D.C. 20231

Sir:

Responsive to the Official Action dated October 11, 2000, the time for filing thereto being extended for one months in accordance with a Petition for Extension submitted concurrently herewith, Applicants respectfully request favorable reconsideration in view of the following remarks.

With regard to the oath and declaration being defective, Applicants believe that the Examiner is mistaken in this regard. Under U.S. practice, the Title in the oath and declaration is used to identify the specification to which the oath and declaration is directed (see MPEP § 601.01(a)). However, this requirement is only applicable at the time the application, and oath and declaration are filed. Applicants' representative in the telephone interview discussed this matter

with the Examiner and after speaking with his supervisor, the Examiner indicated that this objection will be withdrawn.

With regard to the rejections of claims 5-9 under 35 U.S.C. § 102(e) or § 103(a) in view of Ochoa et al. (USP 5,443,983) alone or in combination with Rosenburg, these rejections are deemed to be untenable and are thus respectfully traversed.

Under U.S. practice, to constitute anticipation of the claimed invention, a single prior art reference must disclose each and every material element of the claim. In addition, to establish a prima facie case of obviousness, the cited references either alone or in combination must teach or suggest the invention as a whole, including all the limitations of the claims.

The presently claimed composition comprises "autologous" lymphocytes, which are lymphocytes that are derived from the same patient who ultimately undergoes treatment with such lymphocytes. None of the cited references including newly cited Ochoa et al. (USP 5,443,983) discloses or suggests a composition comprising activated "autologous" lymphocytes. Although the cited Ochoa et al '983 discloses an example in which peripheral blood lymphocytes (PBLs) are collected from the twin brother of a patient (see Example 4 of the reference), the twin brothers are identical in genetics, but have different activated lymphocytes. Further, the cited Ochoa et al. '983 discloses administering the activated lymphocytes, but does not teach or suggest the antiviral activity thereof.

Without being quoted from Ochoa et al. (USP 5,443,983 and USP 5, 316,763) and Rosenberg (USP 4,690,915), it has been known that activated lymphocytes can be prepared by using an anti-CD3 and IL-2, as described in the "Description of the Related Art" section of the

specification. However, the cited references do not teach whether the activated lymphocytes prepared in accordance with the disclosure in the cited references have antiviral effectiveness.

It is now generally recognized in this field that activated lymphocytes, obtained from viral infected patients who develop symptoms from such infections when the lymphocytes of these patient are defeated by the pathogenic virus, should not be expected, as a matter of course, to possess antiviral effectiveness. In general, viral-specific activated lymphocytes are induced to obtained the antiviral effectiveness thereof. There has been a report that the viral-specific activated lymphocytes thus induced have antiviral effectiveness. (Lancet, 345, 9(1995)).

If the activated lymphocytes can easily be prepared in a conventional manner by any person of ordinary skill in the art as pointed out by the Examiner, then the existing preparation method in which viral-specific activated lymphocytes being narrow in available antiviral spectrum are obtained, should be unnecessary. Further, if the methods taught by the present invention had been known or obvious, it should have already been put into practice by one skilled in the art.

In addition, one skilled in the art would not have expected based on the teachings and suggestions of the cited references that the present composition of activated "autologous" lymphocytes would be remarkably and unexpectedly more effective against viral infections than "non-autologous" activated lymphocytes. In other words, it could not have been expected given the teachings of the prior art as noted above that the composition comprising activated "autologous" lymphocytes of the present invention have very wide available antiviral spectrum and shows extremely strong antiviral activity.

Thus, it is apparent from the foregoing that the composition of the present invention and the methods of making and using thereof could not have been anticipated or be obvious over the teachings and suggestions of Ochoa et al. (USP 5,443,983) and Rosenberg (USP 4,690,915) either alone or in combination.

In view of the foregoing remarks, it is respectfully submitted that the Application is now in condition for allowance. Such action is thus respectfully solicited.

If, however, the Examiner has any suggestions for expediting allowance of the application or believes that direct communication with Applicants' attorney will advance the prosecution of this case, the Examiner is invited to contact the undersigned at the telephone number below.

Respectfully submitted,

Teruaki SEKINE et al.

By:_____

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